Overview of needs of vaccine manufacturing capabilities in Latin America and the Caribbean

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Content

- Introduction to PAHO
- Recommendations for Influenza vaccination
- Access to Flu pandemic vaccine
- Vaccine Manufacturing in the Region: current situation and transfer of technology

The Pan American Health Organization (PAHO)

- An international public health agency with more than 100 years of experience in working to improve health and living standards of countries of the Americas.
- It serves as the specialized organization for health of the Inter-American System.
- It also serves as the Regional Office for the Americas of the World Health Organization and enjoys international recognition as part of the United Nations system.

In the vaccine field, PAHO supports countries through technical cooperation :

Expanded Program of Immunization (EPI)

- Progress in protection against basic vaccine-preventable diseases;
- Sustained high national immunization coverage levels,
- Eradicate polio, interrupt endemic measles virus transmission,
- Efforts towards rubella and congenital rubella syndrome elimination.
- Vaccination for age groups outside those usually targeted in the traditional childhood immunization program.
- Introduce seasonal influenza vaccine in adult populations at risk, vaccinate adolescents and adults, men and women for rubella elimination

Implementation and harmonization of sanitary regulation . Pan American Network for the Drug Regulatory Harmonization (PANDRH)

Revolving Fund. acquisition of essential vaccines, syringes, and other related supplies of immunization programs for Member States and institutions

PAHO Technical Advisory Group (TAG) Recommendations on Influenza, 2006

All countries must strengthen their surveillance system to determine:

- the burden of influenza
- the cost-effectiveness of introducing influenza vaccine
- the best vaccination strategy to use and when

All countries to establish a seasonal influenza vaccination policy that aims to vaccinate with seasonal influenza vaccine:

- chronically ill individuals, elderly adults, and pregnant women.
- children aged 6-23 months
- health care workers,

Countries using the vaccine should generate vaccination coverage data and document experiences and lessons learned from targeting high-risk groups.

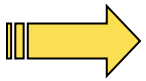
PAHO should continue to promote mechanisms for the transfer of technology to increase Regional capacities in vaccine production and keep track of global supply

Strengthening vaccination against seasonal influenza in the countries of the region

Why?

- **High vaccination coverages against seasonal influenza are the only way to:**

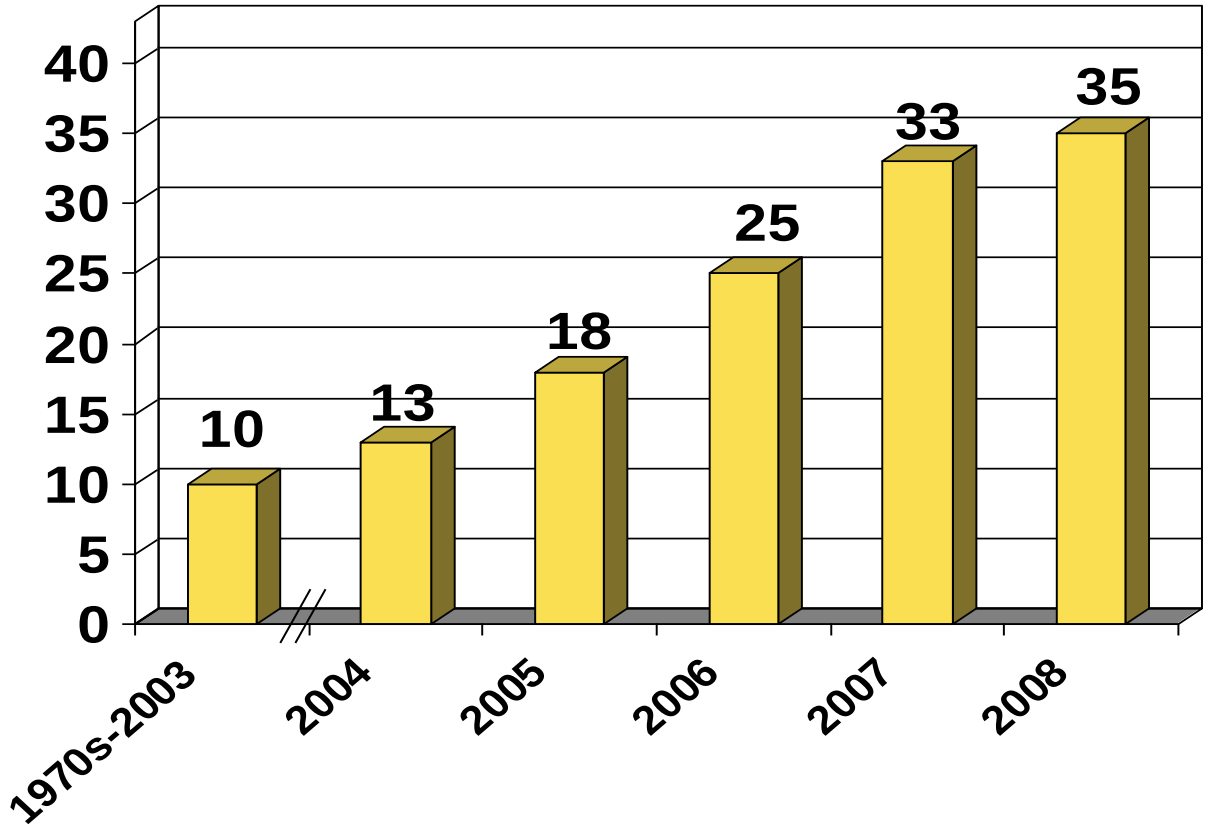
Reduce the disease burden of annual epidemics of influenza. (Resolution 56 of WHA, May 2003 and **TAG recommendations 2004/2006**)



The goal is to vaccinate at least 75% of elderly by 2010

and to increase capacity of production to allow industry to prepare meeting demand in future pandemic

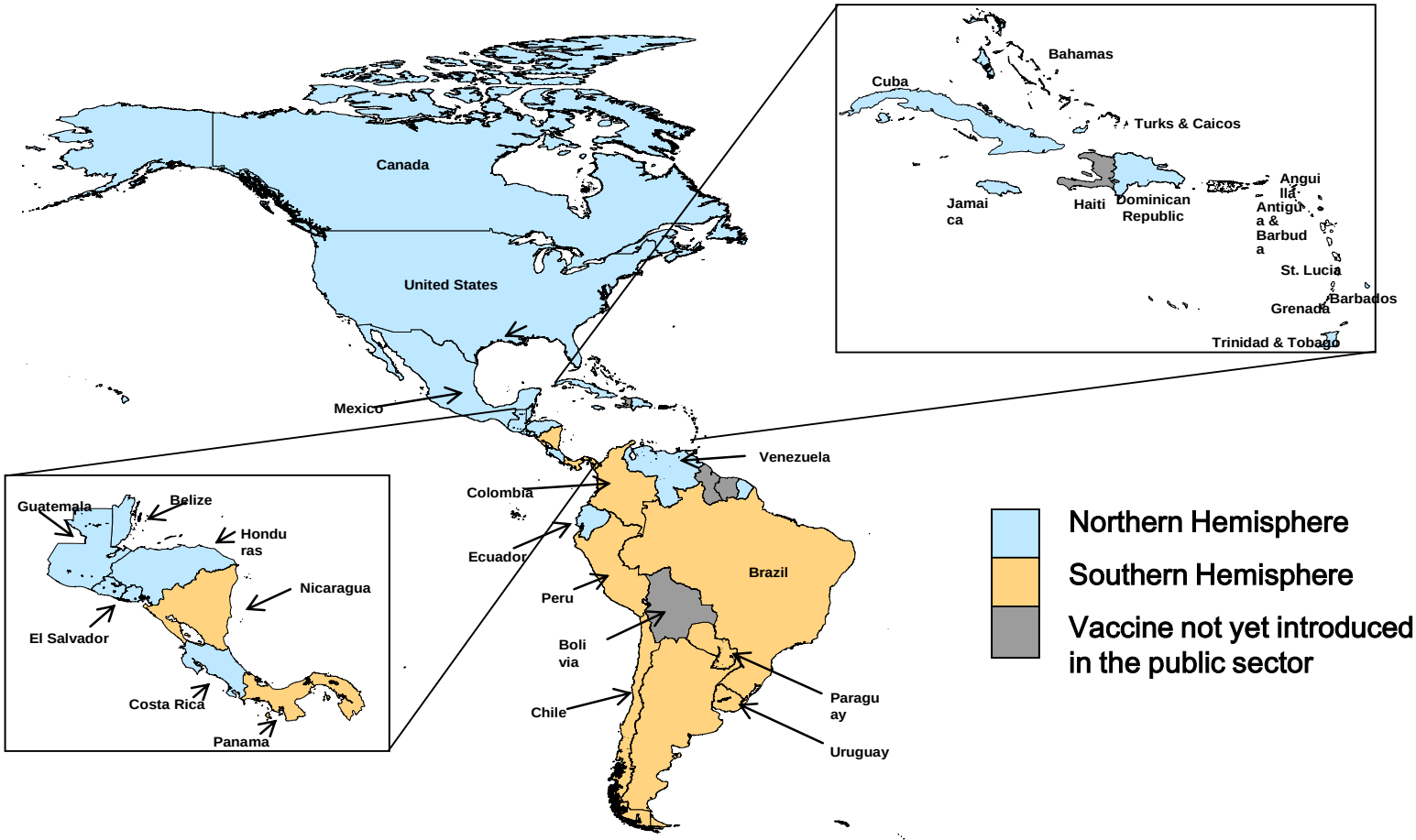
Number of countries and territories in the Americas with vaccination policies against seasonal influenza.



Source: **Country Reports to FCH-IM, PAHO/WHO**

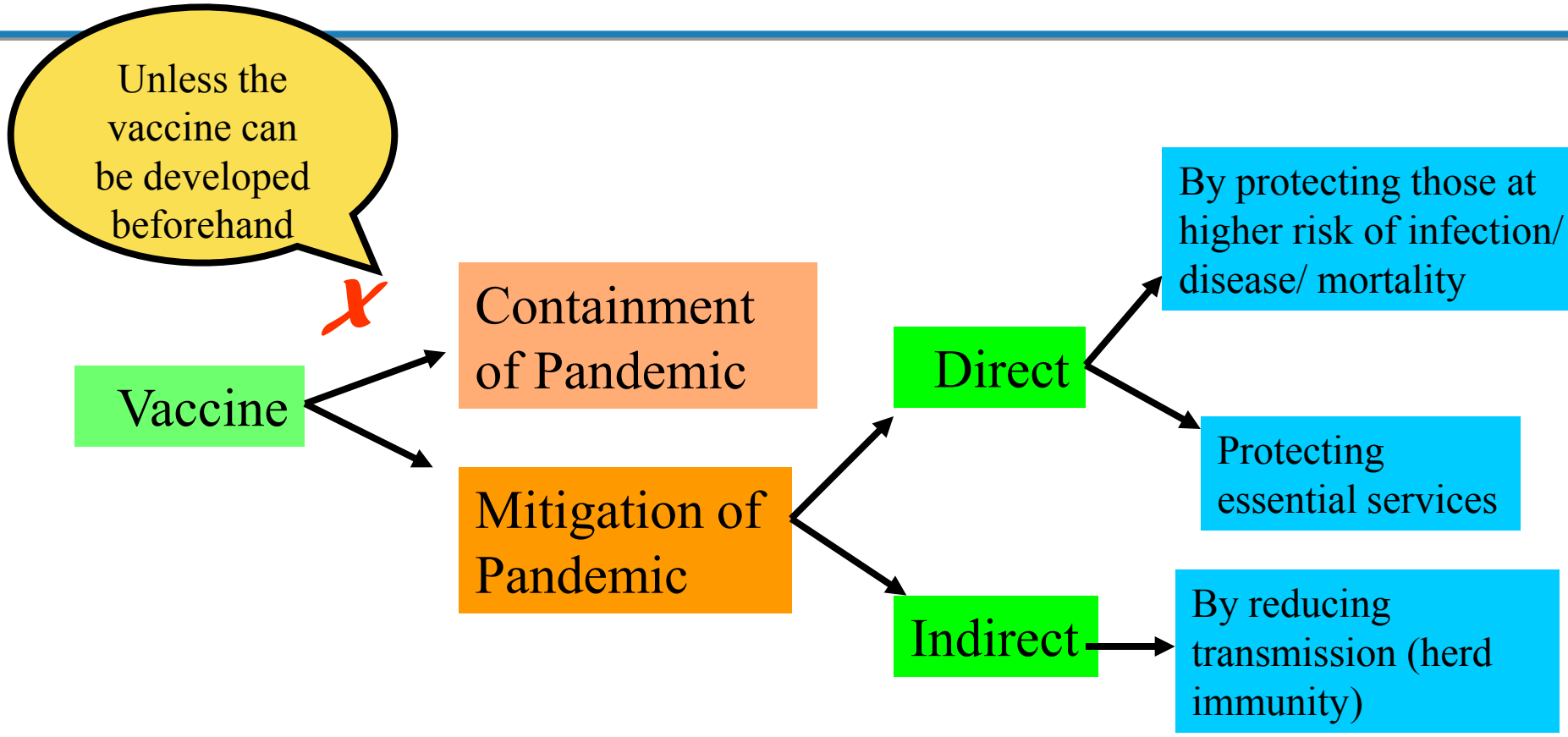
Note: Data was not collected from the French Counrtries (French Guiana, Guadeloupe, Martinique)

Use of seasonal influenza vaccines in the Americas, 2008



Source: Country and territory reports to FCH/IM, PAHO/WHO

Use of vaccine in an influenza pandemic



Vaccine is only one of several tools in mitigation strategy

Recommendations for progressive vaccination against pandemic influenza

SAGE (WHO) 7 July 2009	TAG (PAHO) 24 August 2009
1. Health workers	1. Health workers
2. Pregnant women	2. Pregnant women
3. Population > 6 months with history of chronic diseases	3. Population > 6 months with history of chronic diseases
4. Healthy young adults (>15 and <49 years)	4. Healthy population: * 6 months to 4 years of age * school-age population (> 5 & < 18 yrs.) *young adults (between 19 and 49 years)
5. Healthy Children (< 15 years)	
6. Healthy adults (>49 y <65 years)	
7. Adults > 65 years	

Access to pandemic vaccine by PAHO's Countries

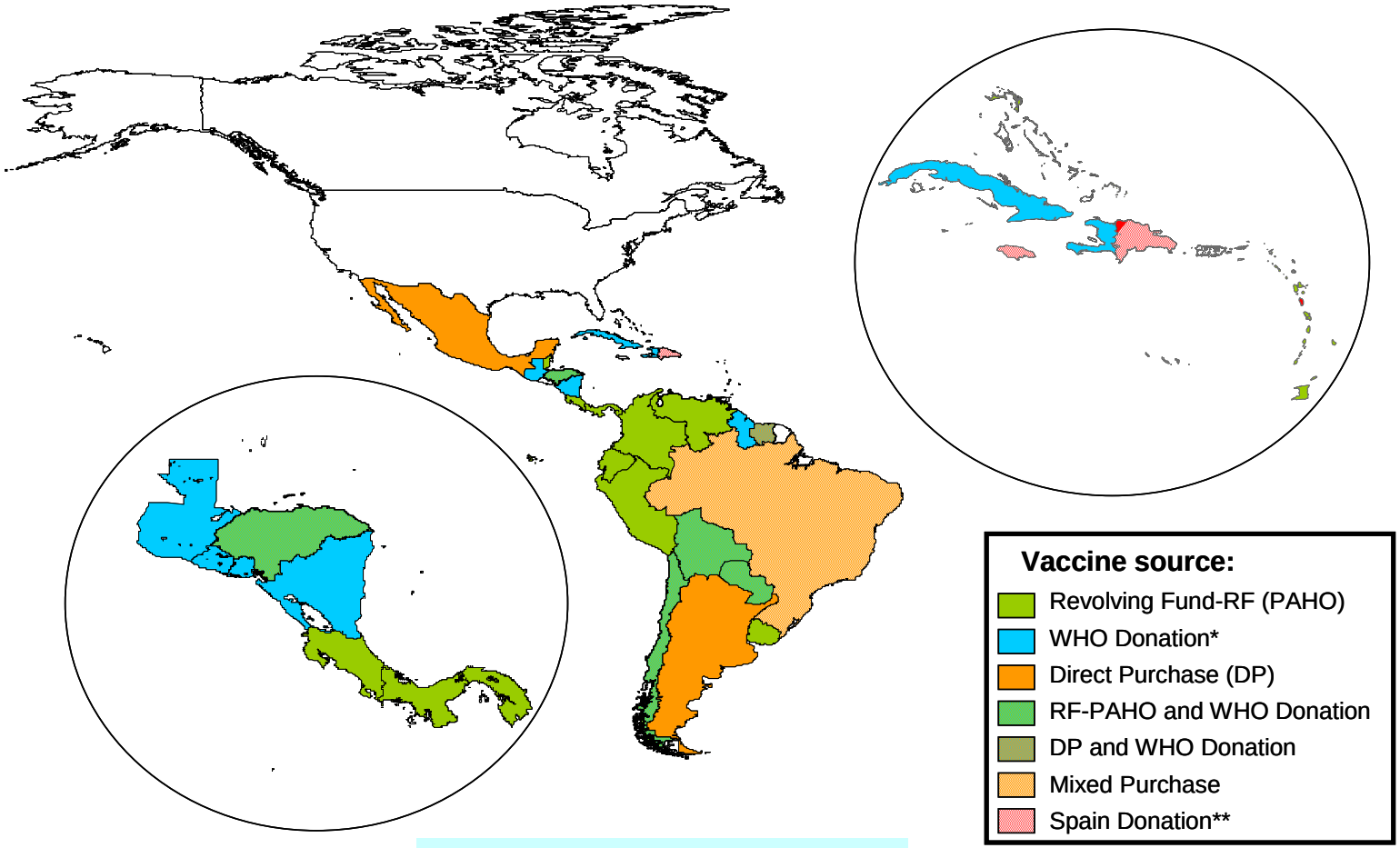
Purchase → PAHO's RF → **24 countries**

Donation → WHO

Bolivia
El Salvador
Guyana
Honduras
Paraguay
Chile
Cuba
Guatemala
Haiti
Nicaragua
Suriname

Deployment: March to June 2010

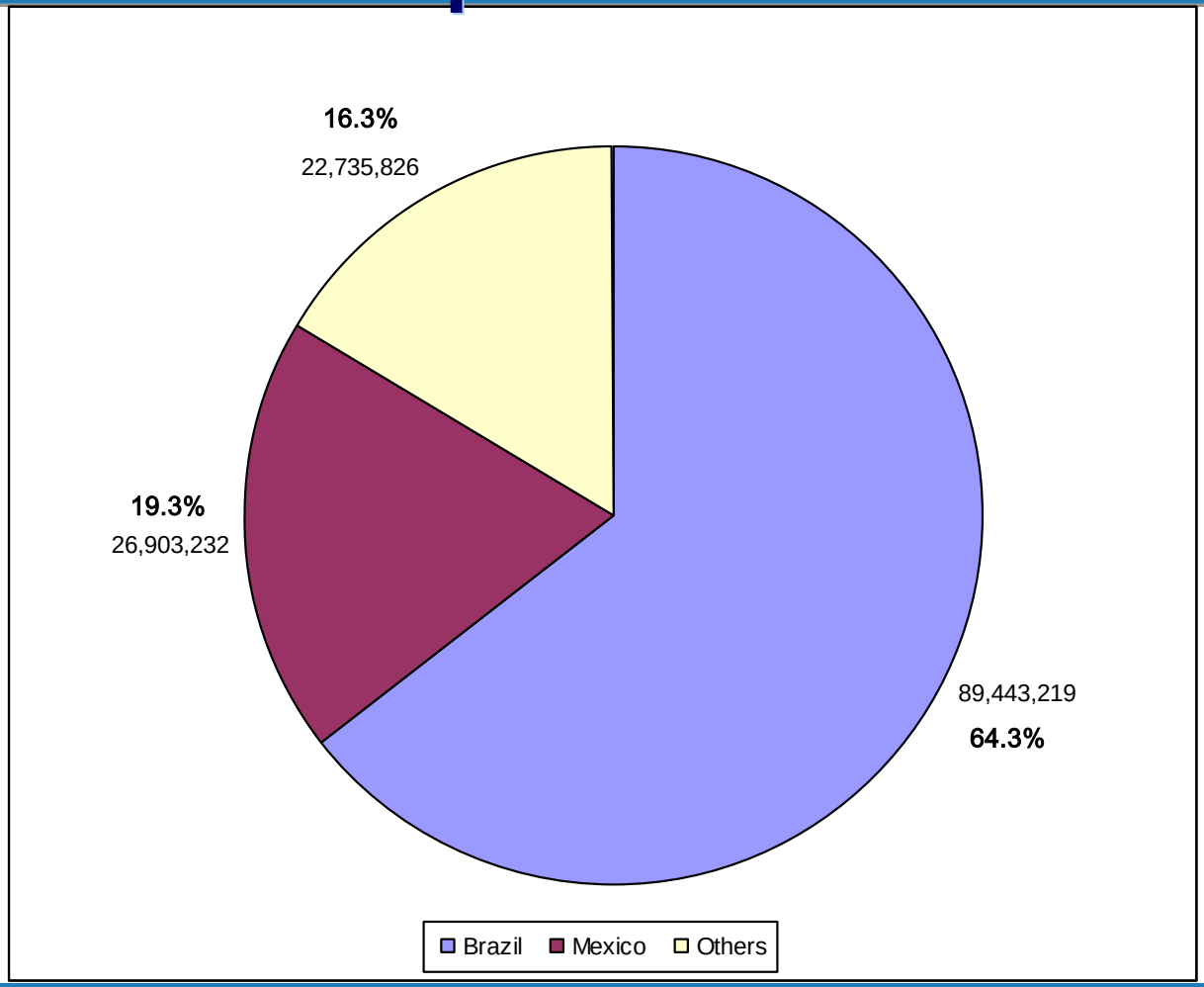
Influenza A (H1N1) Vaccine Access in Latin America and the Caribbean



Aprox. 171 million doses

*Haiti: pending country acceptance of the vaccine donation.
**Spain Donation has not still reached destination countries.

Pandemic Influenza Vaccine. Doses Administered by Country, 13 September 2010



Total doses administered in Latin America and Caribbean: 139,082,277

Conclusions from regional meetings, 2009/2010, sustained with UNASUR (group of 12 South America Countries) and Ministers of Health from Latin America and Caribbean countries:

- Need to generate regional production capacity and regulation of influenza vaccines in order to be able to respond to pandemics;

Pan American Health Organization
Regional Office of the World Health Organization

Main vaccine manufacturing capabilities in the Region

- **BioManguinhos** (Brazil): Yellow fever vaccine, OPV, DTP(Butantan)-HibTT, DTP-HB (Butantan) –Hib, MMR, Meningo A+C (agreement with Cuba), rotavirus. In development: pneumococo (GSK), dengue
- **Butantan** (Brazil): DTP, rabies vaccine, in development HibTT, influenza, rotavirus, acellular pertussis, dengue, BCG recombinant, pneumococo
- **Birmex** (Mexico): OPV, DTP, in development influenza
- **CIGB** (Cuba): Hepatitis B vaccine, Hib-TT (synthetic polysaccharide); in development pneumoccocal vaccine
- **I. Finlay** (Cuba): DTP, DTP-HB-HibTT (CIGB), Meningo ACW13
- In addition **Argentina** (Argentinian Haemorragic Fever vaccine) , **Brazil** (BCG), **Venezuela** (DTP), **Ecuador** (DTP and rabies) though not enough to cover their national demands. Some countries, like **Columbia**, closed production facilities and are looking to reopen them:

  In most cases capacity is just enough to cover national demands, with limited capability for exportation (only for yellow fever and meningo) .

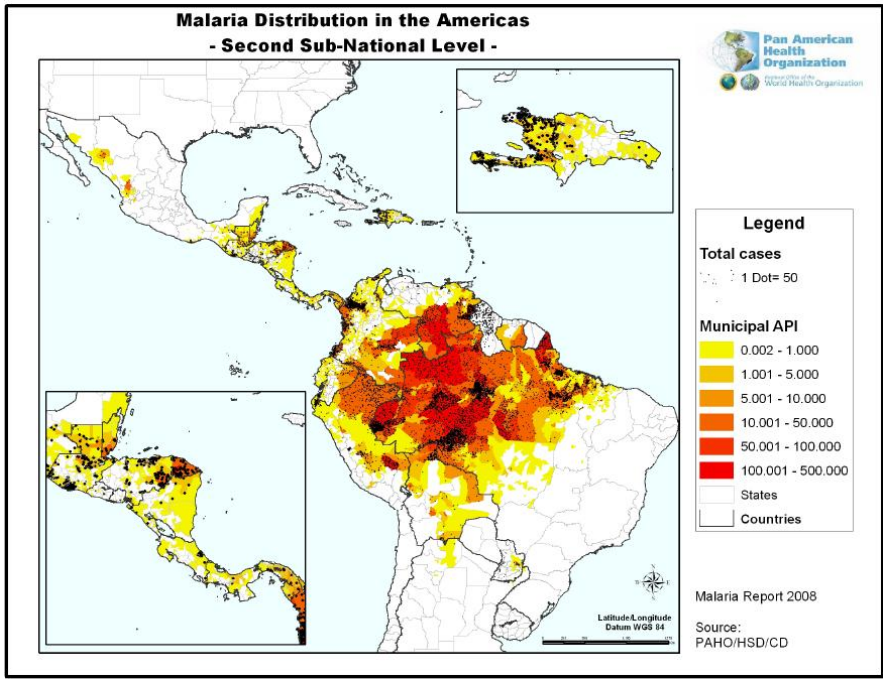
DENGUE 2010

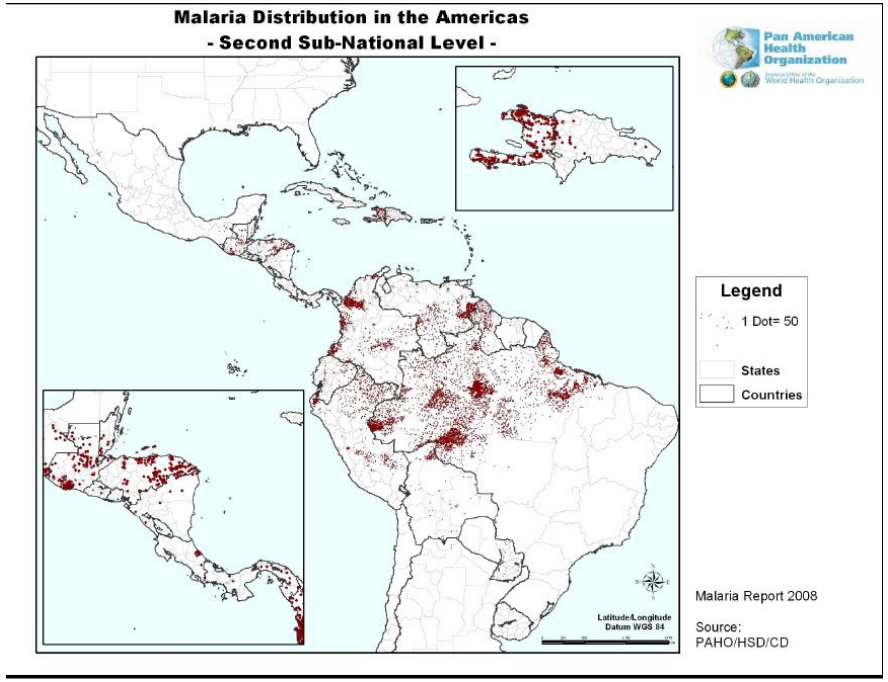
Americas Sub-region	Dengue*	Incidence Rate	Severe Dengue**	Deaths	Letality Rate
North America, Central America & Mexico	144,554	98.4	3,788	101	2.67
Andean	213,204	208.1	15,508	141	0.91
Southern Cone	953,977	393.4	9,725	382	3.93
Hispanic Caribbean	15,894	87.1	724	45	6.22
Caribbean	38,076	479.4	421	11	2.61
TOTAL	1,365,705	260.9	30,166	680	2.25

*Sum of DF + DHF, DSS and/or severe dengue

**Includes DHF, DSS and/or severe dengue

MALARIA


Malaria Distribution in the Americas
- Second Sub-National Level -
Pan American Health Organization
Regional Office of the World Health Organization
Legend
Total cases
1 Dot= 50
Municipal API
0.002 - 1.000
1.001 - 5.000
5.001 - 10.000
10.001 - 50.000
50.001 - 100.000
100.001 - 500.000
States
Countries
Malaria Report 2008
Source:
PAHO/HSD/CD
Latitude/Longitude
Datum WGS 84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Regional vaccines currently needed

Developed within the Region	Not yet developed within the Region
Influenza	Malaria
Pneumococcal vaccines	HPV
Pertussis acellular	Leptospira
Meningo	Others
Dengue	
Leishmania	
Rotavirus	

Transfer technology in the Region

- To BioManguinhos (Brazil) from GSK for: OPV, Hib, MMR, pneumococal conjugated; joint development of inactivated dengue vaccine
- To Butantan (Brazil) from Sanofi-Pasteur for influenza (supported by HHS/WHO), from NIH for rotavirus and for other production processes
- To Birmex (Mexico) from Sanofi-Pasteur for influenza (supported by HHS/WHO)
- Between I. Finlay (Cuba) and BioManguinhos (Brazil) for the production of Meningo A+C+ W135Y X vaccine (supported by WHO)

Conclusions

- PAHO and the Region of the Americas have large experience in vaccination campaigns, including vaccination against seasonal influenza.
- During the Flu pandemic, access to vaccine was limited or late for most of the countries in Latin American and Caribbean countries.
- PAHO's Revolving Fund had a critical role in responding to seasonal and pandemic vaccine demand.
- Experiences of transfer of technology exist and allow regional production. However, the final purpose should be to allow the manufacturers of the Region to become selfsufficient

Thank you

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